

1 Thomas A. Counts (Bar No. 148051)
tomcounts@paulhastings.com
2 Elizabeth A. Dorsi (Bar No. 282285)
elizabethdorsi@paulhastings.com
3 PAUL HASTINGS LLP
55 Second Street, Twenty-Fourth Floor
4 San Francisco, CA 94105-3441
Telephone: 1(415) 856-7000
5 Facsimile: 1(415) 856-7100

6 Elizabeth L. Brann (Bar No. 222873)
elizabethbrann@paulhastings.com
7 PAUL HASTINGS LLP
4747 Executive Drive, 12th Floor
8 San Diego, CA 92121
Telephone: 1(858) 458-3000
9 Facsimile: 1(858) 458-3005

10 Attorneys for Plaintiff
ALIGN TECHNOLOGY, INC.

Timothy P. Cremen (MI Bar No. 478705)
timothycremen@paulhastings.com
(to be admitted *pro hac vice*)
Lisa Y. Leung (Bar No. 277460)
lisaleung@paulhastings.com
PAUL HASTINGS LLP
875 15th Street NW
Washington, D.C. 20005
Telephone: (202) 551-1700
Facsimile: (202) 551-1705

12 UNITED STATES DISTRICT COURT
13 NORTHERN DISTRICT OF CALIFORNIA
14 SAN JOSE DIVISION

16 ALIGN TECHNOLOGY, INC.,

17 Plaintiff,

18 vs.

19 SMILECARECLUB, LLC, CAMELOT SI,
20 LLC D/B/A SHARPERIMAGE.COM, and
BROOKSTONE, INC.,

21 Defendants.

CASE NO. 3:15-cv-04864

**COMPLAINT FOR DAMAGES AND
INJUNCTIVE RELIEF**

JURY TRIAL DEMANDED

1 For its Complaint against Defendants SmileCareClub, LLC (“SmileCareClub”), Camelot
2 SI, LLC d/b/a SharperImage.com (“Sharper Image”), and Brookstone, Inc. (“Brookstone”)
3 (collectively, “Defendants”), Plaintiff Align Technology, Inc. (sometimes hereinafter referred to
4 as “Align”) hereby alleges, by and through its attorney, on personal knowledge as to its own
5 actions and on information and belief as to the actions of others, as follows:

6 **THE PARTIES**

7 1. Plaintiff Align Technology, Inc. (“Align”) is a corporation organized under the
8 laws of Delaware having its principal place of business in Santa Clara, California.

9 2. Upon information and belief, at all relevant times mentioned below, Defendant
10 SmileCareClub, LLC has been a corporation organized under the laws of Tennessee with a
11 principal place of business at 27725 Stansbury Blvd. Ste. 175, Farmington Hills, Michigan.

12 3. Upon information and belief, at all relevant times mentioned below, Defendant
13 Camelot SI, LLC d/b/a SharperImage.com has been a corporation organized under the laws of
14 Michigan with a principal place of business at 27725 Stansbury Blvd. Ste. 175, Farmington Hills,
15 Michigan.

16 4. Upon information and belief, at all relevant times mentioned below, Defendant
17 Brookstone Inc. has been a corporation organized under the laws of Delaware with a principle
18 place of business at One Innovation Way, Murrumbidgee, New Hampshire.

19 **JURISDICTION AND VENUE**

20 5. This lawsuit is an action for patent infringement arising under the patent laws of the
21 United States, 35 U.S.C. §§ 101 et seq. The Court has subject matter jurisdiction over this action
22 pursuant to 28 U.S.C. §§ 1331, 1332, and 1338(a), and 1367.

23 6. On information and belief, Defendants regularly conduct business in this judicial
24 district, and certain of the acts complained of herein occurred in this judicial district.

25 7. Accordingly, the Court has personal jurisdiction over SmileCareClub, Sharper
26 Image, and Brookstone, and venue is proper in this judicial district pursuant to 28 U.S.C.
27 §§ 1391(b) and 1400(b).
28

THE PATENTS-IN-SUIT

8. On November 2, 1999, United States Patent No. 5,975,893 (“the ‘893 patent”), entitled “Method and System for Incrementally Moving Teeth,” was issued to Align. At all relevant times, Align owned the ‘893 patent with full and exclusive right to bring suit to enforce it. A true and correct copy of the ‘893 patent is attached as **Exhibit A**.

9. On April 17, 2001, United States Patent No. 6,217,325 (“the ‘325 patent”), entitled “Method and System for Incrementally Moving Teeth,” was issued to Align. At all relevant times, Align owned the ‘325 patent with full and exclusive right to bring suit to enforce it. A true and correct copy of the ‘325 patent is attached as **Exhibit B**.

10. On April 25, 2001, United States Patent No. 6,602,070 (“the ‘070 patent”), entitled “Systems and Methods for Dental Treatment Planning,” was issued to Align. At all relevant times, Align owned the ‘070 patent with full and exclusive right to bring suit to enforce it. A true and correct copy of the ‘070 patent is attached as **Exhibit C**.

11. On May 8, 2001, United States Patent No. 6,227,850 (“the ‘850 patent”), entitled “Teeth Viewing System,” was issued to Align. At all relevant times, Align owned the ‘850 patent with full and exclusive right to bring suit to enforce it. A true and correct copy of the ‘850 patent is attached as **Exhibit D**.

12. On September 17, 2002, United States Patent No. 6,450,807 (“the ‘807 patent”), entitled “System and Method for Positioning Teeth,” was issued to Align. At all relevant times, Align owned the ‘807 patent with full and exclusive right to bring suit to enforce it. A true and correct copy of the ‘807 patent is attached as **Exhibit E**.

13. On October 29, 2002, United States Patent No. 6,471,511 (“the ‘511 patent”), entitled “Defining Tooth-Moving Appliances Computationally,” was issued to Align. At all relevant times, Align owned the ‘511 patent with full and exclusive right to bring suit to enforce it. A true and correct copy of the ‘511 patent is attached as **Exhibit F**.

14. On September 30, 2003, United States Patent No. 6,626,666 (“the ‘666 patent”), entitled “Method and System for Incrementally Moving Teeth,” was issued to Align. At all

1 relevant times, Align owned the '666 patent with full and exclusive right to bring suit to enforce
2 it. A true and correct copy of the '666 patent is attached as **Exhibit G**.

3 15. On October 7, 2003, United States Patent No. 6,629,840 ("the '840 patent"),
4 entitled "Method and System for Incrementally Moving Teeth," was issued to Align. At all
5 relevant times, Align owned the '840 patent with full and exclusive right to bring suit to enforce
6 it. A true and correct copy of the '840 patent is attached as **Exhibit H**.

7 16. On March 2, 2004, United States Patent No. 6,699,037 ("the '037 patent"), entitled
8 "Method and System for Incrementally Moving Teeth," was issued to Align. At all relevant
9 times, Align owned the '037 patent with full and exclusive right to bring suit to enforce it. A true
10 and correct copy of the '037 patent is attached as **Exhibit I**.

11 17. On April 20, 2004, United States Patent No. 6,722,880 ("the '880 patent"), entitled
12 "Method and System for Incrementally Moving Teeth," was issued to Align. At all relevant
13 times, Align owned the '880 patent with full and exclusive right to bring suit to enforce it. A true
14 and correct copy of the '880 patent is attached as **Exhibit J**.

15 18. On November 14, 2006, United States Patent No. 7,134,874 ("the '874 patent"),
16 entitled "Computer Automated Development of an Orthodontic Treatment Plan and Appliance,"
17 was issued to Align. At all relevant times, Align owned the '874 patent with full and exclusive
18 right to bring suit to enforce it. A true and correct copy of the '874 patent is attached as **Exhibit**
19 **K**.

20 19. On August 25, 2009, United States Patent No. 7,578,674 ("the '674 patent"),
21 entitled "Methods for Correcting Tooth Movements Midcourse in Treatment," was issued to
22 Align. At all relevant times, Align owned the '674 patent with full and exclusive right to bring
23 suit to enforce it. A true and correct copy of the '674 patent is attached as **Exhibit L**.

24 20. On December 6, 2011, United States Patent No. 8,070,487 ("the '487 patent"),
25 entitled "System and Method for Positioning Teeth," was issued to Align. At all relevant times,
26 Align owned the '487 patent with full and exclusive right to bring suit to enforce it. A true and
27 correct copy of the '487 patent is attached as **Exhibit M**.

28

21. On July 15, 2014, United States Patent No. 8,780,106 (“the ‘106 patent”), entitled “Clinician Review of an Orthodontic Treatment Plan and Appliance,” was issued to Align. At all relevant times, Align owned the ‘106 patent with full and exclusive right to bring suit to enforce it. A true and correct copy of the ‘106 patent is attached as **Exhibit N**.

NOTICE OF THE PATENTS IN SUIT

22. Align has complied and complies with the requirements of 35 U.S.C. § 287 by placing a notice of the ‘893, ‘325, ‘070, ‘850, ‘807, ‘511, ‘666, ‘840, ‘037, ‘880, ‘874, ‘674, ‘487, and ‘106 patents (collectively, “patents-in-suit”) on all clear aligner therapy systems it manufactures and sells.

23. On information and belief, Defendants have or will have knowledge of Align’s patent portfolio, including the patents at issue, at least as of the filing date and/or service date of this Complaint.

24. Defendants’ infringement is willful at least as of the filing date and/or service date of this Complaint.

BACKGROUND

25. Align is engaged in the business of, among other things, designing, manufacturing, and marketing the Invisalign System, a proprietary orthodontic method for treating malocclusion using clear orthodontic appliances called aligners. Align received United States Food and Drug Administration (“FDA”) clearance to market the Invisalign System in 1998. At all times material to this action, Align has marketed, distributed, offered for sale, and sold the Invisalign System to orthodontists and general practice dentists (hereinafter “dentist(s)”) in the State of California and throughout the United States.

26. The Invisalign System can be employed in many cases as an alternative to conventional wire braces to treat malocclusion, while offering improved aesthetics, comfort and the ability to maintain oral hygiene, together with potentially reduced overall treatment time, and with a reduced incidence of emergencies requiring intervention by dental professionals during the course of treatment. After an assessment of a patient’s teeth, a dentist can prescribe such clear aligners as part of a course of treatment for malocclusion. Upon choosing such a course, a dentist

1 takes molds, pictures, and/or digital scans of a patient's teeth and orders a system of progressively
2 modified aligners that will gradually realign the patient's teeth from their original position to
3 preferred final positions in accordance with the dentist's prescription. The system of
4 progressively modified aligners is then manufactured, sold, and delivered to the dentist. The
5 dentist provides the progressively modified aligners to the patient in sequence to gradually move
6 the patient's teeth to the preferred positions over the course of treatment.

7 27. All dentists who treat patients using the Invisalign System must attend and
8 complete specialized instructional sessions to become trained Invisalign Providers. Prior to
9 beginning treatment, a dentist takes x-rays, impressions, pictures, and/or digital scans of a
10 patient's teeth and evaluates their overall dental health to determine whether the patient is a
11 suitable candidate for the Invisalign System. During the treatment process, dentists schedule
12 regular appointments with their Invisalign patients to ensure that the treatment is progressing as
13 planned and to provide subsequent sets of aligners.

14 28. Align's FDA clearance to market the Invisalign System specifies that a dentist will
15 oversee each patient's treatment.

16 29. Defendant SmileCareClub competes with Align and recently became engaged in
17 the business of marketing the SmileCareClub system, which also uses clear orthodontic
18 appliances, or aligners, for use in treating malocclusion.

19 30. Under the SmileCareClub system, patients take and submit photographs of their
20 teeth and fill out a medical questionnaire regarding their dental history. After the patients' photos
21 have been reviewed and approved, SmileCareClub sends the patient an Impression Kit and a set
22 of dental history forms to complete. The patient uses the Impression Kit to take impressions of
23 their dentition and returns the impressions and the completed dental history forms to
24 SmileCareClub's lab.

25 31. SmileCareClub's lab creates a custom treatment plan for each patient, which
26 SmileCareClub sends to the patient for review prior to the start of treatment. The treatment plan
27 shows how the patient's teeth are expected to move with each set of aligners and what the
28

1 patient's final teeth position is expected to be. Once the treatment plan is approved, the patient
2 receives a series of aligners to be worn in a specific sequence.

3 32. Upon information and belief, SmileCareClub contracts with dental professionals
4 licensed in the patient's state to oversee each patient's case and to approve the patient's treatment
5 plan. The dental professional does not meet with the patient for an initial evaluation of the
6 patient's dental history, does not take an x-ray of the patient's teeth, and does not meet with the
7 patient in-person during their treatment to evaluate the patient's progress. In certain cases, the
8 dental professional will conduct an Interproximal Reduction to remove enamel from between the
9 patient's teeth to create the necessary space for the teeth to move to their ideal position.

10 33. Upon information and belief, SmileCareClub does not have a dental professional
11 independently verify a patient's self-reporting of their medical or dental history.

12 34. Upon information and belief, SmileCareClub received FDA clearance as a
13 Repackager/Relabeler of invisible aligners that are cleared by the FDA for manufacturing by a
14 separate entity.

15 35. Upon information and belief, SmileCareClub does not develop the treatment plans
16 or manufacture the aligners itself for SmileCareClub patients.

17 36. Defendant SmileCareClub markets and sells the SmileCareClub system directly to
18 consumers on its website SmileCareClub.com.

19 37. Defendant Sharper Image markets and sells the SmileCareClub system directly to
20 consumers on its website SharperImage.com.

21 38. Defendant Brookstone markets and sells the SmileCareClub system directly to
22 consumers on its website Brookstone.com.

23 39. At all times material to this action, Defendants have marketed, distributed, offered
24 for sale, and sold the SmileCareClub system to customers in the State of California, and
25 throughout the United States, in competition with the Invisalign System that is marketed,
26 distributed, offered for sale, and sold by Align.

COUNT ONE:
INFRINGEMENT OF THE '893 PATENT

40. Align realleges and incorporates herein the allegations contained in the preceding paragraphs of this Complaint as if fully set forth herein.

41. In violation of 35 U.S.C. § 271(a), Defendants have infringed and are still infringing, either literally and/or under the doctrine of equivalents, the '893 patent by making, offering to sell, and/or selling clear aligner therapy systems covered by at least claim 1 thereof.

42. In violation of 35 U.S.C. § 271(g), Defendants have infringed and are still infringing, either literally and/or under the doctrine of equivalents, the '893 patent by offering to sell and selling clear aligner therapy systems made by the processes covered by at least claim 12 thereof.

43. Upon information and belief, Defendants have willfully infringed the '893 patent.

44. As a result of Defendants' infringement, Align has suffered and will suffer damages.

45. Upon information and belief, Defendants' acts of infringement of the '893 patent will continue after service of this Complaint unless enjoined by the Court.

46. Unless Defendants are enjoined by the Court from continuing their infringement of the '893 patent, Align will suffer additional irreparable damages and impairment of the value of its patent rights. Thus, Align is entitled to preliminary and permanent injunctions against further infringement.

COUNT TWO:
INFRINGEMENT OF THE '325 PATENT

47. Align realleges and incorporates herein the allegations contained in the preceding paragraphs of this Complaint as if fully set forth herein.

48. In violation of 35 U.S.C. § 271(a), at least Defendant SmileCareClub has infringed and are still infringing, either literally and/or under the doctrine of equivalents, at least claim 1 of the '325 patent by performing in the United States in the United States and without authority every step of the patented invention by providing clear aligner therapy systems.

1 its patent rights. Thus, Align is entitled to preliminary and permanent injunctions against further
2 infringement.

3 **COUNT FOUR:**
4 **INFRINGEMENT OF THE '850 PATENT**

5 60. Align realleges and incorporates herein the allegations contained in the preceding
6 paragraphs of this Complaint as if fully set forth herein.

7 61. In violation of 35 U.S.C. § 271(a), at least Defendant SmileCareClub has infringed
8 and are still infringing, either literally and/or under the doctrine of equivalents, at least claim 1 of
9 the '850 patent by performing in the United States in the United States and without authority
10 every step of the patented invention by providing clear aligner therapy systems.

11 62. Upon information and belief, Defendants have willfully infringed the '850 patent.

12 63. As a result of Defendants' infringement, Align has suffered and will suffer
13 damages.

14 64. Upon information and belief, Defendants' acts of infringement of the '850 patent
15 will continue after service of this Complaint unless enjoined by the Court.

16 65. Unless Defendants are enjoined by the Court from continuing their infringement of
17 the '850 patent, Align will suffer additional irreparable damages and impairment of the value of
18 its patent rights. Thus, Align is entitled to preliminary and permanent injunctions against further
19 infringement.

20 **COUNT FIVE:**
21 **INFRINGEMENT OF THE '807 PATENT**

22 66. Align realleges and incorporates herein the allegations contained in the preceding
23 paragraphs of this Complaint as if fully set forth herein.

24 67. In violation of 35 U.S.C. § 271(a), at least Defendant SmileCareClub has infringed
25 and are still infringing, either literally and/or under the doctrine of equivalents, at least claim 1 of
26 the '807 patent by performing in the United States in the United States and without authority
27 every step of the patented invention by providing clear aligner therapy systems.
28

78. Upon information and belief, Defendants' acts of infringement of the '511 patent will continue after service of this Complaint unless enjoined by the Court.

79. Unless Defendants are enjoined by the Court from continuing their infringement of the '511 patent, Align will suffer additional irreparable damages and impairment of the value of its patent rights. Thus, Align is entitled to preliminary and permanent injunctions against further infringement.

COUNT SEVEN:
INFRINGEMENT OF THE '666 PATENT

80. Align realleges and incorporates herein the allegations contained in the preceding paragraphs of this Complaint as if fully set forth herein.

81. In violation of 35 U.S.C. § 271(a), at least Defendant SmileCareClub has infringed and are still infringing, either literally and/or under the doctrine of equivalents, at least claim 1 of the '666 patent by performing in the United States in the United States and without authority every step of the patented invention by providing clear aligner therapy systems.

82. Upon information and belief, Defendants have willfully infringed the '666 patent.

83. As a result of Defendants' infringement, Align has suffered and will suffer damages.

84. Upon information and belief, Defendants' acts of infringement of the '666 patent will continue after service of this Complaint unless enjoined by the Court.

85. Unless Defendants are enjoined by the Court from continuing their infringement of the '666 patent, Align will suffer additional irreparable damages and impairment of the value of its patent rights. Thus, Align is entitled to preliminary and permanent injunctions against further infringement.

COUNT EIGHT:
INFRINGEMENT OF THE '840 PATENT

86. Align realleges and incorporates herein the allegations contained in the preceding paragraphs of this Complaint as if fully set forth herein.

1 sell and selling clear aligner therapy systems made by the processes covered by at least claim 1
2 thereof.

3 96. Upon information and belief, Defendants has willfully infringed the '037 patent.

4 97. As a result of Defendants' infringement, Align has suffered and will suffer
5 damages.

6 98. Upon information and belief, Defendants' acts of infringement of the '037 patent
7 will continue after service of this Complaint unless enjoined by the Court.

8 99. Unless Defendants are enjoined by the Court from continuing their infringement of
9 the '037 patent, Align will suffer additional irreparable damages and impairment of the value of
10 its patent rights. Thus, Align is entitled to preliminary and permanent injunctions against further
11 infringement.

12 **COUNT TEN:**
13 **INFRINGEMENT OF THE '880 PATENT**

14 100. Align realleges and incorporates herein the allegations contained in the preceding
15 paragraphs of this Complaint as if fully set forth herein.

16 101. In violation of 35 U.S.C. § 271(a), at least Defendant SmileCareClub has infringed
17 and are still infringing, either literally and/or under the doctrine of equivalents, at least claim 1 of
18 the '880 patent by performing in the United States in the United States and without authority
19 every step of the patented invention by providing clear aligner therapy systems.

20 102. In violation of 35 U.S.C. § 271(g), Defendants have infringed and are still
21 infringing, either literally and/or under the doctrine of equivalents, the '880 patent by offering to
22 sell and selling clear aligner therapy systems made by the processes covered by at least claim 1
23 thereof.

24 103. Upon information and belief, Defendants have willfully infringed the '880 patent.

25 104. As a result of Defendants' infringement, Align has suffered and will suffer
26 damages.

27 105. Upon information and belief, Defendants' acts of infringement of the '880 patent
28 will continue after service of this Complaint unless enjoined by the Court.

106. Unless Defendants are enjoined by the Court from continuing their infringement of the '880 patent, Align will suffer additional irreparable damages and impairment of the value of its patent rights. Thus, Align is entitled to preliminary and permanent injunctions against further infringement.

COUNT ELEVEN:
INFRINGEMENT OF THE '874 PATENT

107. Align realleges and incorporates herein the allegations contained in the preceding paragraphs of this Complaint as if fully set forth herein.

108. In violation of 35 U.S.C. § 271(a), at least Defendant SmileCareClub has infringed and are still infringing, either literally and/or under the doctrine of equivalents, at least claim 1 of the '874 patent by performing in the United States in the United States and without authority every step of the patented invention by providing clear aligner therapy systems.

109. In violation of 35 U.S.C. § 271(g), Defendants have infringed and are still infringing, either literally and/or under the doctrine of equivalents, the '874 patent by offering to sell and selling clear aligner therapy systems made by the processes covered by at least claim 1 thereof.

110. Upon information and belief, Defendants have willfully infringed the '874 patent.

111. As a result of Defendants' infringement, Align has suffered and will suffer damages.

112. Upon information and belief, Defendants' acts of infringement of the '874 patent will continue after service of this Complaint unless enjoined by the Court.

113. Unless Defendants are enjoined by the Court from continuing their infringement of the '874 patent, Align will suffer additional irreparable damages and impairment of the value of its patent rights. Thus, Align is entitled to preliminary and permanent injunctions against further infringement.

COUNT TWELVE:
INFRINGEMENT OF THE '674 PATENT

114. Align realleges and incorporates herein the allegations contained in the preceding paragraphs of this Complaint as if fully set forth herein.

115. In violation of 35 U.S.C. § 271(a), at least Defendant SmileCareClub has infringed and are still infringing, either literally and/or under the doctrine of equivalents, at least claim 17 of the '674 patent by performing in the United States in the United States and without authority every step of the patented invention by providing clear aligner therapy systems.

116. In violation of 35 U.S.C. § 271(g), Defendants have infringed and are still infringing, either literally and/or under the doctrine of equivalents, the '674 patent by offering to sell and selling clear aligner therapy systems made by the processes covered by at least claim 17 thereof.

117. Upon information and belief, Defendants have willfully infringed the '674 patent.

118. As a result of Defendants' infringement, Align has suffered and will suffer damages.

119. Upon information and belief, Defendants' acts of infringement of the '674 patent will continue after service of this Complaint unless enjoined by the Court.

120. Unless Defendants are enjoined by the Court from continuing their infringement of the '674 patent, Align will suffer additional irreparable damages and impairment of the value of its patent rights. Thus, Align is entitled to preliminary and permanent injunctions against further infringement.

COUNT THIRTEEN:
INFRINGEMENT OF THE '487 PATENT

121. Align realleges and incorporates herein the allegations contained in the preceding paragraphs of this Complaint as if fully set forth herein.

122. In violation of 35 U.S.C. § 271(a), at least Defendant SmileCareClub has infringed and are still infringing, either literally and/or under the doctrine of equivalents, at least claim 10

1 of the '487 patent by performing in the United States in the United States and without authority
 2 every step of the patented invention by providing clear aligner therapy systems.

3 123. In violation of 35 U.S.C. § 271(g), Defendants have infringed and are still
 4 infringing, either literally and/or under the doctrine of equivalents, the '487 patent by offering to
 5 sell and selling clear aligner therapy systems made by the processes covered by at least claim 10
 6 thereof.

7 124. In violation of 35 U.S.C. § 271, Defendants have infringed and continue to
 8 infringe the '487 patent by contributing to or actively inducing the infringement by others, such
 9 as Defendants' customers, of the '487 patent by providing clear aligner therapy systems.

10 125. Upon information and belief, Defendants have willfully infringed the '487 patent.

11 126. As a result of Defendants' infringement, Align has suffered and will suffer
 12 damages.

13 127. Upon information and belief, Defendants' acts of infringement of the '487 patent
 14 will continue after service of this Complaint unless enjoined by the Court.

15 128. Unless Defendants are enjoined by the Court from continuing their infringement of
 16 the '487 patent, Align will suffer additional irreparable damages and impairment of the value of
 17 its patent rights. Thus, Align is entitled to preliminary and permanent injunctions against further
 18 infringement.

19 **COUNT FOURTEEN:**
 20 **INFRINGEMENT OF THE '106 PATENT**

21 129. Align realleges and incorporates herein the allegations contained in the preceding
 22 paragraphs of this Complaint as if fully set forth herein.

23 130. In violation of 35 U.S.C. § 271(a), Defendants have infringed and are still
 24 infringing, either literally and/or under the doctrine of equivalents, at least claim 7 of the '106
 25 patent by performing in the United States in the United States and without authority every step of
 26 the patented invention by providing clear aligner therapy systems.

27 131. In violation of 35 U.S.C. § 271(g), Defendants have infringed and are still
 28 infringing, either literally and/or under the doctrine of equivalents, the '106 patent by offering to

1 sell and selling clear aligner therapy systems made by the processes covered by at least claim 7
2 thereof.

3 132. Upon information and belief, Defendants have willfully infringed the '106 patent.

4 133. As a result of Defendants' infringement, Align has suffered and will suffer
5 damages.

6 134. Upon information and belief, Defendants' acts of infringement of the '106 patent
7 will continue after service of this Complaint unless enjoined by the Court.

8 135. Unless Defendants are enjoined by the Court from continuing their infringement of
9 the '106 patent, Align will suffer additional irreparable damages and impairment of the value of
10 its patent rights. Thus, Align is entitled to preliminary and permanent injunctions against further
11 infringement.

12 **COUNT FIFTEEN:**
FALSE AND MISLEADING ADVERTISING IN VIOLATION OF SECTION 43(A) OF
THE LANHAM ACT, 15 U.S.C. § 1125(A)

13 136. Align realleges and incorporates herein the allegations contained in the preceding
14 paragraphs of this Complaint as if fully set forth herein.

15 137. SmileCareClub advertises on its website that "[b]y working with remote licensed
16 dental professionals to prescribe treatment and oversee your case, we eliminate a majority of the
17 costs associated with other invisible aligner systems . . . all without sacrificing quality."
18 Additionally, SmileCareClub advertises that customers will receive "identical results for less than
19 50% of the others."

20 138. SmileCareClub further advertises that SmileCareClub Invisible Aligners are "FDA
21 Approved."

22 139. Sharper Image currently advertises on its website that the SmileCareClub system is
23 "convenient, safe and affordable, and all under the care of a licensed dental professional who
24 prescribes and oversees treatment virtually." Sharper Image previously advertised that the
25 SmileCareClub system is "easy, convenient and this consumer-friendly model lowers costs, and
26 the savings are passed on to you. Smile Care Club has pioneered teledentistry by matching
27
28

1 patients with Smile Care Club dental professionals for virtual office visits to prescribe and
2 oversee treatment.”

3 140. Brookstone advertises on its website that the SmileCareClub system is “easy,
4 convenient and this consumer-friendly model lowers costs, and the savings are passed on to you.
5 Smile Care Club has pioneered teledentistry by matching patients with Smile Care Club dental
6 professionals for virtual office visits to prescribe and oversee treatment.”

7 141. Defendants’ advertising misleads customers into believing that the SmileCareClub
8 product is of the same quality, and is just as safe, as the Invisalign System.

9 142. The SmileCareClub system is not identical to the Invisalign System because
10 customers using the SmileCareClub system are not physically evaluated or monitored throughout
11 treatment by a dentist. Oversight by a dentist is necessary to protect a patient’s dental health and
12 monitor their treatment progress.

13 143. Dentists play an important role in determining a patient’s suitability for treatment
14 and prescribing treatment, as well as in monitoring the patient’s dental health and treatment
15 progress. For example, without oversight by a dentist to determine if they are good candidates for
16 treatment, customers of the SmileCareClub system are at risk of undiagnosed tooth decay,
17 periodontal disease, decalcification (permanent markings on the patient’s teeth), or inflammation
18 of the gums. Customers are also at risk of existing dental restorations, such as crowns and
19 bridges, becoming dislodged. Moreover, dentists monitor patients for extreme side effects such
20 as root resorption, where the tooth’s roots become shorter, possibly leading to the loss of the
21 tooth.

22 144. Defendants’ adoption of SmileCareClub’s claim that it is “FDA Approved” is
23 deceptive and misleading for several reasons. First, SmileCareClub’s claim that SmileCareClub
24 invisible aligners are “FDA Approved” is false. SmileCareClub aligners have not been subject to
25 the FDA Premarket approval (PMA) process. SmileCareClub’s advertising misleads customers
26 into believing that the FDA has analyzed the SmileCareClub clear aligner system and verified
27 that it is a safe and effective product when no such scientific and regulatory review has occurred.
28 Second, for this same reason, SmileCareClub’s use of the “FDA Approved” logo on its marketing

1 materials is improper, deceptive and misleading. Third, until very recently, SmileCareClub's
2 purported "FDA approval" was only as a repackager/relabeler of dental positioners designed to
3 prevent teeth from moving, not sequential aligners intended to move teeth. Thus, for that period
4 of time, SmileCareClub was distributing a product that was not properly registered with the FDA,
5 let alone "FDA Approved." Fourth, even now, SmileCareClub is only registered with the FDA as
6 a repackager/relabeler, not as a manufacturer or specification developer, and is limited to the
7 activities associated with this registration. SmileCareClub's fundamental alteration of the
8 doctor/patient relationship renders SmileCareClub's comparison to other FDA cleared devices
9 like the Invisalign System inapt. The existing FDA cleared devices contemplate dental
10 professionals meeting in-person with patients to diagnose the patient, obtain accurate impressions
11 of the patient's existing dentition, develop a treatment plan, and monitor the ongoing treatment
12 through regular in-person contact. The elimination of these components changes the risk profile
13 of the device and affects the safety and effectiveness of the device. SmileCareClub's product
14 lacks all of these critical components of the current FDA cleared devices.

15 145. Defendants' advertising is literally false, deceptive, and misleading representations
16 of fact in violation of Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a).

17 146. Upon information and belief, Defendants' false advertising is likely to influence
18 purchasing decisions of customers by representing that customers can receive the same product as
19 Align's Invisalign System for a reduced cost.

20 147. As a result of Defendants' false and misleading advertising, Align has suffered and
21 will continue to suffer irreparable and monetary damages in an amount to be determined at trial.
22 Align has and will suffer direct monetary damages from loss of sales from customers who select
23 the SmileCareClub system instead of the Invisalign System. Align also has and will suffer
24 reputational damage from instances in which customers have negative experiences with the
25 SmileCareClub system that are attributed to problems with all clear aligner systems.

26 148. Upon information and belief, Defendants' acts of false and misleading advertising
27 will continue after service of this Complaint unless enjoined by the Court.
28

1 149. Unless Defendants are enjoined by the Court from continuing their false and
2 misleading advertising, Align will suffer additional irreparable harm. Align has no adequate
3 remedy at law for these wrongs and injuries. Thus, Align is entitled to preliminary and
4 permanent injunctions against further false advertising.

5
6 **COUNT SIXTEEN:**
7 **UNFAIR COMPETITION (CAL. BUS. & PROF. CODE § 17200)**

8 150. Align realleges and incorporates herein the allegations contained in the preceding
9 paragraphs of this Complaint as if fully set forth herein.

10 151. Defendants' false and misleading advertising and related actions constitute
11 intentional unfair competition in violation of Align's rights under California Business and
12 Professions Code § 17200, causing injury to Align and its products' sales, business relationships,
13 reputation, and goodwill.

14 152. As a result of Defendants' false and misleading advertising, Align has suffered and
15 will continue to suffer irreparable and monetary damages in an amount to be determined at trial.

16 153. As a result of Defendants' false and misleading advertising and related actions,
17 Defendants have benefited from increased sales, profits, market share, reputation, and goodwill,
18 some of which Align would otherwise have earned but for Defendants' actions.

19 154. Defendants knew, or reasonably should have known, that the increased sales,
20 market share, reputation, and goodwill that they received resulted directly from their literally
21 false, deceptive, and misleading advertising. Defendants have acted intentionally, willfully,
22 deliberately, maliciously, egregiously, and in bad faith to injure Align. Align has no adequate
23 remedy at law for such injuries. Thus, Align is entitled to permanent injunction against further
24 false and misleading advertising.

25 155. It would be unjust for Defendants to retain the benefits conferred upon them as a
26 result of their literally false, deceptive, and misleading advertising, and Defendants' continuance
27 of such practices while knowing of the resulting harm.
28

PRAYER FOR RELIEF

Therefore, Align prays for the following relief:

- a) a finding that Defendants have infringed each of the patents-in-suit;
- b) a preliminary and final injunction against the continuing infringement pursuant to 35 U.S.C. § 283;
- c) damages adequate to compensate Align for Defendants' infringement of the '893, '325, '070, '850, '807, '511, '666, '840, '037, '880, '874, '674, '487, and '106 patents pursuant to 35 U.S.C. § 284;
- d) a judgment that the infringement was willful and treble damages pursuant to 35 U.S.C. § 284;
- e) a declaration that this case is an exceptional case within the meaning of 35 U.S.C. § 285 and that Align be awarded attorney fees, costs, and expenses incurred in connection with this action;
- f) an accounting for damages;
- g) interest and costs; and
- h) such other and additional relief as the Court deems just and proper.

DEMAND FOR JURY TRIAL

In accordance with Rule 38 of the Federal Rules of Civil Procedure, Align respectfully demands a jury trial of all issues triable to a jury in this action.

Date: October 22, 2015

Respectfully submitted,

PAUL HASTINGS LLP
THOMAS A. COUNTS
ELIZABETH A. DORSI

By: /s/ Thomas A. Counts
Thomas A. Counts

Thomas A. Counts (Bar No. 148051)
tomcounts@paulhastings.com
Elizabeth A. Dorsi (Bar No. 282285)
elizabethdorsi@paulhastings.com
PAUL HASTINGS LLP

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

55 Second Street, Twenty-Fourth Floor
San Francisco, CA 94105-3441
Telephone: 1(415) 856-7000
Facsimile: 1(415) 856-7100

Elizabeth L. Brann (Bar No. 222873)
elizabethbrann@paulhastings.com
PAUL HASTINGS LLP
4747 Executive Drive, 12th Floor
San Diego, CA 92121
Telephone: 1(858) 458-3000
Facsimile: 1(858) 458-3005

Timothy P. Cremen (Bar No. 478705)
timothycremen@paulhastings.com
(to be admitted *pro hac vice*)
Lisa Y. Leung (Bar No. 277460)
lisaleung@paulhastings.com
PAUL HASTINGS LLP
875 15th Street NW
Washington, D.C. 20005
Telephone: (202) 551-1700
Facsimile: (202) 551-1705